LABEL IN PART: (Carton) "Elemin Supreme Formula G & J Multiple Vitamins This Package Contains a 60 Day Supply SUPREME FORMULA is packaged in sanitary, hermetically sealed Pocket Paks, each containing 2 Elemin Mineral Tablets and 1 G & J Multiple Vitamin Tablet."

CHARGE: 502 (f) (1)—the labeling of the article failed to bear adequate directions for use in the treatment of the diseases, symptoms, and conditions for which the article was intended, namely, colds, sinus infections, heart trouble, diabetes, asthma, high blood pressure, ulcerated stomach, and arthritis.

PLEA: Not guilty.

DISPOSITION: The case came on trial before the court without a jury on 2–17–56, and was concluded on the same day. The court took the case under advisement; on 3–28–56, the court handed down a finding of guilty against the defendant. On 6–18–56, the court suspended imposition of sentence and placed the defendant on probation for 1 year.

5063. Vitamin and mineral food supplement. (F. D. C. No. 38452. S. Nos. 7854/5 M.)

QUANTITY: 46 cases, each containing 12 packages and each package containing 1 186-tablet bottle of *mineral tablets* and 1 62-capsule bottle of *vitamin capsules*, at Oklahoma City, Okla., in possession of K. V. Products Co.

SHIPPED: 7–29–55, from Glendale, Calif.

LIBELED: 9–20–55, W. Dist. Okla.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use for the purposes for which the article was intended, namely, in the treatment of rheumatism, asthma, heart conditions, loss of hair, nosebleed, and for cleaning the blood, which were the conditions and purposes for which the article was offered orally by Mrs. Bertha Lee Wilson, a representative of K. V. Products Co.

DISPOSITION: 6–7–56. Default—destruction.

5064. Cal-O-Dine. (F. D. C. No. 38461. S. No. 24–750 M.)

QUANTITY: 26 2-qt. jugs at Seattle, Wash., in possession of Emil Gellerman.

SHIPPED: 8–15–55, from Alameda, Calif.

LABEL IN PART: "Cal-O-Dine * * * A Dietary Source of Iodine Consists of Potassium Iodide In Processed Sea Water."

LIBELED: 9–29–55, W. Dist. Wash.

CHARGE: 502 (f) (1)—the labeling of the article, while held for sale, failed to bear adequate directions for use for the purposes for which it was intended, namely, in the treatment of heart disease, arthritis, stomach troubles, ulcers, paralysis, cataracts, tumors, dizzy spells, pernicious anemia, goiters, burns, and bruises, which were the conditions for which the article was offered by Emil Gellerman.

DISPOSITION: 8–28–56. Default—destruction.

DRUGS AND DEVICES ACTIONABLE BECAUSE OF DEVIATION FROM OFFICIAL OR OWN STANDARDS

5065. Various drugs. (Inj. No. 280.)

COMPLAINT FOR INJUNCTION FILED: 4–29–54, E. Dist. N. Y., against Bonded Laboratories, Inc., Brooklyn, N. Y., and Hans Lowey, president of the corporation.

CHARGE: The complaint alleged that the defendants had been and still were engaged in manufacturing, selling, and shipping directly to places outside the State of New York, and delivering to a Brooklyn firm for shipment to places outside the State of New York, various drugs which were adulterated and misbranded as follows:

501 (b)—a portion of the drugs purported to be and were represented as drugs, the names of which are recognized in official compendia, namely, the United States Pharmacopeia and the National Formulary; and the strength of the drugs differed from the standards set forth in such compendia;

501 (c)—the strength of a portion of the drugs differed from that which they purported and were represented to possess;

501 (d) (2)—certain substances had been substituted for a portion of the drugs;

502 (a)—the labeling of a portion of the drugs bore false and misleading statements with respect to the nature and quantity of the ingredients contained in the drugs.

The complaint alleged further that the adulterated and misbranded conditions of the drugs resulted from deficiencies in the ingredients of the drugs, the presence of ingredients in amounts in excess of those declared on the labels or required by the standards set forth in the official compendia, and the substitution of certain substances for the drugs involved.

For example, examination of samples from interstate shipment and from deliveries for interstate shipment made by the defendants of certain articles of drugs, namely, *Visnico Pulvoids, Siccoid hematinic tablets, sulfadiazine tablets, aminophylline-phenobarbital tablets, diethylstilbestrol tablets, ammonium chloride tablets, phenobarbital tablets, Dietabs No. 1, Dietabs No. 2,* and *Dietabs No. 3,* disclosed that the *Visnico Pulvoids* contained only 68 percent of the declared amount of potassium nitrate and not more than 77 percent of the declared amount of sodium nitrate; that the *Siccoid hematinic tablets* contained not more than 66 percent of the declared amount of vitamin C; that two lots of the *sulfadiazine tablets* were not only deficient in sulfadiazine to the extent that they contained from 20 percent to 21.2 percent of the declared amount of sulfadiazine, but they were also of a different composition from that declared on their labels by reason of the substitution in part of a large amount of sulfathiazole for the sulfadiazine ingredient; that one other lot of the *sulfadiazine tablets* contained less than 80 percent of the declared amount of sulfadiazine; that the *aminophylline-phenobarbital tablets* contained at least 19 percent more phenobarbital than the ¼ grain of phenobarbital declared on the label and at least 10 percent more aminophylline than the 1½ grain of aminophylline declared on the label; that the *diethylstilbestrol tablets* contained 73.4 percent of the declared amount of diethylstilbestrol; that the *ammonium chloride tablets* contained not more than 68 percent of the declared amount of ammonium chloride; that the *phenobarbital tablets* contained 27 percent more phenobarbital than the ½ grain of phenobarbital declared on the label; that the *Dietabs No. 1* contained not more than 61.2 percent of the declared amount of amphetamine sulfate; that the *Dietabs No. 2* contained not more than 54.6 percent of the declared amount of amphetamine sulfate; and that the *Dietabs No. 3* contained not more than 62.4 percent of the declared amount of amphetamine sulfate.

The complaint alleged further that the defendants were well aware that their activities were violative of the Act. Several inspections were made of the defendants' plant in Brooklyn, N. Y., by inspectors of the Food and Drug

Administration between 2–13–51 and 2–8–54, at which times the defendants were informed of certain inadequacies in their control system for the manufacture of the articles, namely, the failure to assay the raw materials used; the lack of care in identifying containers of raw materials, batches of the articles during processing, and the finished articles; the lack of an adequate checking system to insure that the proper amounts of the various chemicals were put into the batches of the chemicals being processed; and the practice of making very few assays of the finished articles. The defendants were warned that such inadequacies would result in errors of composition and labeling with respect to the articles manufactured, and that such inadequacies would result also in the articles being adulterated and misbranded as aforesaid. The defendants had been warned also by 4 seizures and by a notice of hearing. Despite such warnings, the defendants continued to introduce and deliver for introduction into interstate commerce drugs which were adulterated and misbranded as described above.

The complaint alleged also that certain vitamin preparations were adulterated and misbranded under the provisions of the law applicable to foods, as reported in notices of judgment on foods, No. 23244.

DISPOSITION: On 4–29–54, the court entered a temporary restraining order under which the defendants were temporarily restrained from commission of the acts complained of. Thereafter, with the consent of the parties, the temporary restraining order was continued in effect pending the final determination of the matter.

On 12–12–55, a consent decree of permanent injunction was entered against Bonded Laboratories, Inc., its agents, servants, employees, and representatives, and all and any persons in active concert or participation with them, and against the president of Bonded Laboratories, Inc., whether in connection with such corporation or independently, enjoining them against introducing or delivering for introduction into interstate commerce any foods and drugs which are adulterated and misbranded as charged in the complaint, and which are manufactured, prepared, and packed by Bonded Laboratories, Inc., without the utilization of good controls necessary to the end that an article of proper composition is purchased and shipped.

5066. Aspirin tablets. (F. D. C. No. 35661. S. No. 52–623 L.)

QUANTITY: 2 50,000-tablet drums at Greystone Park, N. J.

SHIPPED: 7–14–53, from Brooklyn, N. Y., by Bonded Laboratories, Inc.

LIBELED: 9–25–53, Dist. N. J.

CHARGE: 501 (b)—the article purported to be and was represented as a drug, "Aspirin Tablets," the name of which is recognized in the United States Pharmacopeia, an official compendium; and, when shipped, its quality and purity fell below the standard set forth in such compendium in that the article had a strong odor of acetic acid, many of the tablets were discolored, and a portion of the tablets contained less than 5 grains of acetylsalicylic acid.

DISPOSITION: 10–30–53. Default—destruction.

5067. Sulfadiazine tablets and diethylstilbestrol tablets. (F. D. C. No. 36103. S. Nos. 50–555 L, 50–557 L.)

QUANTITY: 17 100-tablet btls. of *sulfadiazine tablets* and 33 100-tablet btls. of *diethylstilbestrol tablets* at Newark, N. J.

SHIPPED: 7–2–53, from Brooklyn, N. Y., by Bonded Laboratories, Inc.